

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

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IN RE YASMIN AND YAZ	:	3:09-md-02100-DRH-PMF
(DROSPIRENONE) MARKETING, SALES	:	
PRACTICES AND RELEVANT PRODUCTS	:	MDL No. 2100
LIABILITY LITIGATION	:	
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	:	Hon. David R. Herndon
This Document Applies To All Actions	:	
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CASE MANAGEMENT ORDER NO. 18

**(DEFENDANTS' FACT SHEET ("DFS") AND THE PRODUCTION OF SALES
REPRESENTATIVE CUSTODIAL FILES)**

A. DEFENDANTS' FACT SHEET

1. Consistent with the provisions of Amended CMO No. 9, in every case currently part of or later transferred or filed into the *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Product Liability* litigation, MDL 2100, Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Schering Pharma AG, Barr Laboratories, Inc. and Teva Pharmaceuticals USA, Inc. shall provide fully responsive answers and documents to the Defendant Fact Sheet ("DFS"), in the form attached hereto as Exhibit "1," to Plaintiff's individual attorney as identified in the Plaintiff Fact Sheet, with a copy of the DFS (without documents) to Plaintiffs Liaison counsel in paragraph A(8) below. As used herein the term "fully responsive" shall mean that each question in the DFS will be answered in detail and to the extent that an answer refers to a document, Bates-page number or a range of Bates page number shall be supplied which identify the document being referred to and produced. Moreover, all

documents supplied shall be Bates-numbered and shall be provided with the DFS consistent with CMO No. 13 Governing the Format of Production .

2. Within **forty-five (45) days** of the date of receiving a PFS that contains the “*Core Criteria*” as defined below,¹ Defendants shall serve a DFS and all documents that are responsive to the DFS in an electronic format (except as provided in Section B below with regard to Sales Representative Custodial files, the production of which shall be staggered). If a PFS containing the “Core Criteria” has been served on Defendants prior to the date of this Order, Defendants shall have **forty-five (45) days** from the date of entry of this Order to complete and serve a DFS consistent with the provisions herein.

3. “Core Criteria” includes answers to the following question in the PFS attached to CMO 12 as Exhibit 1 :

- a) **PFS Sect I:** Questions 1, 2 & 3 (Identification of Plaintiff and case the PFS is submitted in);
- b) **PFS Sect III:** Question 4 (Identification of each pharmacy [name, address and the approximate years used] that has dispensed medication in the past ten (10) years, and corresponding signed authorizations. The lack of a pharmacy phone number or zip code is not considered a deficiency for the purpose of the production of a DFS; and
- c) **PFS Sect IX:** Questions 1, 2 and 3 and corresponding signed authorizations (product use/prescriber information). The lack of a phone number

¹ The Parties expressly recognize that the “Core Criteria” used to trigger the production of a DFS are less than what is required for a PFS to be “substantially complete” as that term is defined in CMO 12 § C and agree that the use of these “Core Criteria” is in no way meant to modify that definition of “substantially complete.”

or zip code is not considered a deficiency for the purpose of the production of a DFS.

d) **PFS Sect X**: Questions 1(a) and (d) and corresponding signed authorizations (alleged injury information). It is sufficient in answering Question 1(a), for a Plaintiff to provide a short description of the injury alleged *i.e.* "Blood Clot", "Pulmonary Embolism," or "PE", "Deep Vein Thrombosis" or "DVT", or "Gallbladder Injury," "Stroke", or "Heart Attack." It is sufficient for Plaintiff to provide the month and year for her injury and Defendants shall not withhold a DFS if the month and year is provided.

e) **Sect XIII**: Plaintiff's signature on PFS.

4. Defendants shall not delay the production of a DFS based on deficient "*Core Criteria*" absent good-cause. If Defendants contend that any PFS does not satisfactorily include the "*Core Criteria*," then Defendants shall, within either (i) ten **(10) days** after its receipt of the PFS, or (ii) ten (10) days after the date of this order with respect to any PFS served on Defendants prior to the date of this Order, notify Plaintiff's individual counsel by E-mail (with a copy of the E-mail to Plaintiff's Liaison counsel) of any alleged deficiency in the "*Core Criteria*" for processing the DFS. Failure to notify Plaintiff's counsel within the ten (10) days shall mean that Defendants will provide a complete and verified DFS within forty-five (45) days after its receipt of the PFS.

5. If Defendants fail to provide a complete and verified DFS within the time period specified by paragraph 2, above, notice shall be given to Defendants by E-mail from either Plaintiff's individual counsel or Plaintiffs' Liaison Counsel and Defendants shall have twenty-one

(21) days to cure the deficiency. Any claim of alleged deficiency with a DFS shall be directed by E-mail to:

Amy J. Roy
Eckert Seamans Cherin & Mellott, LLC
44th Floor, 600 Grant Street
Pittsburgh, PA 15219
YazDFS@eckertseamans.com

6. Each Defendant named in Plaintiff's Complaint that has been properly served shall have a representative from the company sign the completed DFS and provide an executed declaration attesting that the information contained therein is true and correct to the best of the Defendant's knowledge, information and belief, formed after due diligence and reasonable inquiry.

7. A completed DFS shall be considered to be interrogatory answers and responses to requests for production under the Federal Rules of Civil Procedure, and will be governed by the standards applicable to written discovery under the Federal Rules of Civil Procedure. The interrogatories and requests for production in the DFS shall be answered without objection.

8. Defendants shall serve a copy of each DFS to Plaintiff's individual representative counsel as identified in the PFS and to Plaintiffs' Liaison Counsel via E-mail (without attached documents produced) at:

Roger C. Denton
Schlichter Bogard & Denton
100 S. 4th Street, Suite 900
St. Louis, MO 63102
yazdfs@uselaws.com

B. THE PRODUCTION OF SALES REPRESENTATIVE CUSTODIAL FILES

1. As set forth in Section II. B. 6 of the DFS attached hereto as Exhibit 1, for all Sales Representatives or detail persons identified in Section II (B) (2) of a particular DFS, copies of the sales representatives' custodial files are to be produced no later than 60 days in advance of the first deposition noticed by the defendants specific to the action to which that DFS pertains.

2. Defendants shall produce to an individual Plaintiff's attorney a Sales Representative's Custodial File reasonably promptly upon completion of collection and review of that individual file by Defendants' counsel, and shall not wait to produce one Sales Representative Custodial file until all custodial files are collected and reviewed that pertain to an individual case. Nothing in this Case Management Order shall preclude the Plaintiff from noticing or taking any case-specific depositions without regard to the production of a sales representative's custodial file.

3. "Sales Representative Custodial" files may include all written materials, video and or audio tapes in the possession of the Sales Representative identified in the DFS that had contact with Plaintiff's Dispensing/Prescribing Health Care Provider including but not limited to:

- (a) training materials (including videotapes and/or audio-tapes) related to physician detailing and obstacle handling, including any workbooks or forms completed by the Sales Representative at the time that he or she had Yaz, Yasmin, Ocella, Gianvi related responsibilities;
- (b) E-mails, bulletins, memoranda, reports, activity reports, call notes, belief notes, tactical plans, voice-mail transcripts or summaries, meeting or conference summaries;

- (c) materials obtained at any national, regional, district or other sales meeting, including but not limited to written materials, videos and/or audio tape;
- (d) physician prescribing data and/or ratings;
- (e) incentive plans (to the extent the incentive plans specifically relate to Yaz, Yasmin, Ocella, Gianvi or drugs that are cross-promoted);
- (f) promotional or cross-promotional and marketing materials related to Yaz, Yasmin, Ocella, Gianvi;
- (g) all hardcopy generic training materials (including videotapes and audiotapes) related to physician detailing and obstacle handling, including any workbooks or forms completed by the Sales Representative;
- (h) all documents signed by the Sales Representative reflecting Defendants business and or ethics practices and or policies at the time that he or she had Yaz, Yasmin, Ocella, Gianvi related responsibilities;
- (i) all documents provided to Plaintiff's Dispensing/Prescribing Health Care Provider;
- (j) reports of goal attainment; plans or action;
- (k) materials and information regarding budgets available for speaker's programs;
- (l) materials relating to speakers programs;
- (m) material relating to any testing taken by the Sales Representatives; and,
- (n) all communication by and between the Sales Representatives and managers.

4. Custodial files include all non-identical copies of the materials described above that are contained in the records of the identified Sales Representatives, whether those materials are stored and maintained by Defendants in its facilities, a third-party storage vendor, or at the home or automobile of the Sales Representative.

5. If there are any additions or changes to the DFS when Defendants produce the Sales Representative Custodial file, Defendants shall provide Plaintiff's individual counsel and to Plaintiff Liaison counsel at the E-mail address set forth in paragraph A(8) above with an Amended DFS clearly indicating the changes to the originally produced DFS. If there are no changes or additions to the DFS, Defendants shall indicate as much in the letter transmitting the Sales Representative Custodial file.

C. BELLWETHER CASES

The parties shall meet and confer regarding any amendments to the provisions of this Order that may be appropriate with respect to any Bellwether cases identified by the Court subsequent to the date of this Order, and present the Court with any appropriate amendments pertinent to such Bellwether cases.

IT IS SO ORDERED.

Dated: June 9, 2010

/s/ David R. Herndon

**Honorable David R. Herndon
Chief Judge, United States District Court**